PATENT SPECIFICATION

DRAWINGS ATTACHED

878,788

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International Classification:—A61b.

COMPLETE SPECIFICATION

Vaccination Package and method of making same

I, SOL ROY ROSENTHAL, a citizen of the United States of America, of 230 East Delaware Place, Chicago, Illinois, United States of America, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to a new method of vaccination and inoculation for skin testing, and to a novel package by which such inoculation or vaccination may be quickly and easily carried out.

The present invention provides a package for use in transcutaneous inoculation, comprising a substantially rigid backing member adapted to be held in the fingers, a skin perforating member secured to said backing member and having a plurality of needle-like projections extending therefrom for simultaneously puncturing the skin at a plurality of points when said backing member is pressed by the fingers against the skin, and protective cover means removably secured to said backing member and covering said skin perforating member for protecting and maintaining said needle-like projections sterile prior to use.

The present invention also provides a method of manufacturing a device for use in transcutaneous inoculation, comprising the steps of providing a thin metal plate having a plurality of needle-like projections thereon, dipping said projections into a liquid antigenic substance, and then drying said substance on said projections.

For many years it has been the common practice to vaccinate with various antigens by inoculating with a syringe and an injecting needle intracutaneously, subcutaneously, or intramuscularly. For smallpox vaccination the virus has commonly been introduced transcutaneously by depositing a film of the liquid vaccine on the skin and puncturing or scratching the skin through the vaccine with an ordinary needle or the like over a relatively small area. In each of these commonly used methods the vaccine is concentrated in a small area and, as a result thereof, these prior methods have often led to either generalized or localized reactions of a severe and undesirable character.

The present inventor some years ago, discovered that such undesirable reactions could often be avoided and vaccination could be more quickly and easily accomplished by introducing a vaccine into the skin transcutaneously by multiple punctures of identical character and depth distributed over a substantially greater area of the skin than had been employed in prior vaccination methods, and on December 2, 1952, applicant was granted United States Patent No. 2,619,962 on a vaccination appliance by which vaccinations could easily be made employing this multiple puncture technique. The vaccination appliance disclosed in said patent comprises a thin metal plate having needles punched therefrom and projecting in parallel relationship from one side thereof outwardly beyond the level of the adjacent surfaces of the plate. As disclosed in the patent, vaccination was accomplished by cleaning the surface of the skin with alcohol or the like and a quantity of vaccine, in either liquid or powdered form, was then spread over the area where the vaccination was to be effected. The vaccination appliance was then placed against the surface to which the vaccine had been applied and it was pressed inwardly, thereby forming a plurality of punctures of the skin with a resulting transcutaneous injection of the vaccine at the site of each puncture, without scarification of the skin.

The vaccination appliance of our prior patent is now being widely used with excellent results, and the present invention is related thereto in certain respects in that the present new method of inocculation and vaccination, and the present new package by which vaccination and inoculation for skin testing may be effected more easily and quickly utilizes a form of the appliance broadly

covered by our prior patent.

One of the principal objects of the present invention is to provide a prepared package for effecting transcutaneous inoculation, which package is complete in itself and is of a nature such that it may be readily stored in large numbers without special precautions and may be supplied to physicians and hospitals in the same manner as ordinary medical supplies. Another object of the invention is to provide a vaccination or inoculation package of the kind just stated which may be quickly and easily used, and is ready for use immediately upon opening of the package. Still another object of the invention is to provide such a package which renders unnecessary the usual use of a needle and syringe for withdrawing vaccines and skin testing materials from ampules and the usual reconstituting of such vaccines and testing materials, and renders unnecessary the use and handling of liquid or powdered vaccines and skin testing materials by the physician or nurse, thereby greatly simplifying vaccination procedures and eliminating or greatly reducing the chance for human error during the making of vaccinations and skin tests.

The new prepared package, in one of its forms, comprises a substantially rigid backing member having secured thereto a thin metal plate having a plurality of needle-like projections punched therefrom, and with a dried antigenic substance on each of the needle-like projections. The backing member, in this form of the package, has removably secured thereto a substantially rigid, imperforate, bubble-like cap that completely covers the metal plate and its needle-like projections so as to protect the projections and prevent contamination of the dried antigenic substance thereon prior to use of the package in inoculation. In order to make a vaccination or skin testing inoculation with the package, the physician merely needs to clean the skin area where the vaccination or inoculation is to be made. He then opens the package by removing the cover, whereupon, by gripping the backing member in his fingers, he presses the needle-like projections of the thin metal plate against the skin, thereby simultaneously puncturing the skin at a plurality of points. He holds the device in this position only for a short time until the lymph or other body fluids in the deeper recesses of the skin dissolve the antigenic substance off the embedded projections. It is desirable, although not necessarily essential, that the thin metal plate be rotated slightly in a circular motion, but without scarification, while the needle-like projections are embedded in the skin, thereby tending to wipe all of the antigenic substance off the projections and deposit the same in or under the skin. The vaccination or inoculation, in any event, will then have been completed and the instrument can be withdrawn and discarded. It will immediately be appreciated that the entire vaccination or inoculation procedure will, therefore, require only a few moments when one of the present new packages is employed, and that no clean-up of equipment will be needed or involved.

Another object of the present invention is to provide a new method of producing a device for use in vaccination and inoculation, comprising providing a thin metal plate having a plurality of needle-like projections thereon, dipping the projections into a liquid antigenic substance, and then drying the substance on the projections preparatory to making a vaccination or skin testing inoculation in the manner just explained above.

Other objects and advantages of the present invention will be apparent from the following description of a preferred form of the package, with variations, and a preferred manner for carrying out the method. In the accompanying drawings:

Fig. 1 shows a perspective view of the arm of a patient upon which a vaccination or skin test inoculation is being made with the use of one of our new vaccination or inoculation packages;

Fig. 2 is a side view in elevation of one of our new packages;

Fig. 3 is a top plan view thereof with the bubble-like cover removed;

Fig. 4 is an enlarged cross-sectional view taken substantially along the line 4—4 in Fig. 3, but showing the cover in place;

Fig. 5 is a similar view taken substantially along the line 5—5 in Fig. 3;

Figs. 6 and 7 are similar to Fig. 5, but they show variations in the way in which the thin metal plate may be secured to the backing member, and they show a variation in the way in which the cap or cover may be secured in protective position upon the backing member;

Fig. 8 is an enlarged perspective view of one of the thin metal plates prior to mounting upon a backing member;

Fig. 9 is a similar view of another form of thin metal plate which may be employed in vaccination packages in accordance with the present invention;

Fig. 10 is a greatly enlarged view of one form of needle-like projection on one of the thin metal plates, showing the projection as being perforated in order to increase the amount of antigenic material that may readily be applied thereto and dried thereon pursuant to the present invention;

Fig. 11 is a view similar to Fig. 10, but showing a needle-like projection pitted, as by sandblasting, in order to increase the amount of antigenic material that may readily be applied thereto; and

Fig. 12 is a similar view of another needle-like projection, showing the surface of the projection scarified as by scratching.

As illustrated in the drawings, the package

of the present invention is comprised of a single piece backing member 11 which has a generally flat or planar central portion 12 with a pair of wing-like projections 13 and 14 extending from opposite sides or ends thereof so that the backing member may easily be held and manipulated by the fingers. The backing member 11 is preferably formed of a suitable moldable plastic material, such for example as polystyrene, polyethylene, nylon or the material known under the Registered Trade Mark "Teflon". In the form of the package illustrated in Fig. 5 the central area of the central portion 12 of the backing member is somewhat thicker than the wing-like projections 13 and 14 so that the upper side of the central portion 12 provides a raised platform 12a having a peripheral overhang 12b, beneath which there is a peripheral slot 12c. This overhang 12b and the slot 12c are adapted to receive an inwardly directed flange or lip 15a of a bubble-like cover 15 which is preferably transparent and which, like the backing member 11, may be formed of a suitable molded synthetic plastic material.

In the form of the package shown in Figs. 3 to 5, the raised platform 12a has a pair of recesses 12d formed therein. The recesses 12d are of gradually increasing depth, as best seen in Fig. 5, and the opposite side walls of each recess are provided with projecting nibs or detents 12e, beneath which there are received tongues 16a formed integrally on the opposite ends of a thin metal plate 16. The underside of the metal plate thus lies flat against the surface of the raised platform 12a and is retained in this position by the presence of the tongues 16a in the recesses 12d and by the detents 12e which secure the tongues in the recesses.

The plate 16, as best seen in Fig. 8, may be generally of rectangular configuration with four or more sharply pointed needle-like projections 16b punched from the central portion of the plate, leaving a rectangular opening 16c at the centre of the plate. The needle-like projections are preferably of uniform length and size and they project at right angles from the plane of the thin metal plate 16 from 1 to about 4 mms., depending upon the type of vaccination to be accomplished.

Each of the needle-like projections 16b is coated with a dried antigenic substance 17, as will be more fully explained below, and the cover or cap 15 protects the projections 16b and prevents contamination of the dried antigenic substance prior to use of the package in effecting a vaccination.

The forms of the package shown in Figs. 6 and 7 are similar to the form shown in Figs. 3 to 5 except as to the way in which the cover is applied to the backing member 11 and the manner in which the metal plate 16 is secured to the backing member. In Figs. 6 and 7 the top of the central portion 12 of the backing member is flat and without the raised platform 12a shown in Fig. 5, and the cover 15 is not provided with a lap or flange around its periphery. On the contrary, the peripheral edge 15b of the bubble-like cap or cover 15 in these modifications is plain and is removably received in a tight fit downwardly into a slot 12f formed in the upper surface of the central portion 12 of the backing member. The metal plate 16 shown in Fig. 6 differs from that shown in Figs. 3 to 5 and 8 in that the tongues 16a are apertured and the plate is secured to the central portion 12 of the backing member by means of rivets 18 which extend through the apertures of the tongues and through the body of the central portion 12 of the backing member, the rivets preferably having flat heads at their ends adjacent the metal plate 16. In Fig. 7, on the other hand, the tongues on the metal plate 16 are somewhat longer than those shown in Figs. 3 to 6 and 8 and provide tabs 16d which extend to the rear side of the backing member through apertures 12g provided in the central portion 12 thereof, where the free ends of the tabs 16d are bent over, as shown in Fig. 7, in order to secure the metal plate upon the backing member.

The present vaccination packages are useful in a great variety of inoculations with allergons and antigens of different kinds. Vaccines, for example, which may be injected into a patient with the use of the present packages include the vaccines for whooping cough, polio, rabies, yellow fever, smallpox and others including the vaccine of Calmette and Guerin, commonly called "BCG", for tuberculosis. Testing materials that may be injected by the use of the present packages include (but are not limited to) coccidioidin, blastomycin, histoplasmin, lepromin and tuberculin, as well as allergens for foods and pollens. In the injection of certain of these materials it may be desirable to use a package employing a somewhat larger metal plate with additional needle-like projections thereon, and an example of such a plate is shown in Fig. 9 where the plate is provided with thirty-six projections 16a rather than the four shown in Fig. 8. Various sizes of plates may, of course, be employed with backing members 11 of different sizes, depending upon the vaccination requirements.

In preparing the packages, the metal plates 16 are cleaned and the needle-like projections 16b thereof are thereupon coated with the desired wet antigenic substance by merely dipping the projections into a liquid solution of the substance or by cataphoresic deposition of the substance upon the projections. The amount of the wet substance retained upon the projections may be increased by a scarification of the surfaces of the projections. This may be done in several ways. For example, in Fig. 10 the projections 16b are shown to have

been pierced by a plurality of very small openings 16e; in Fig. 11 the surfaces of the projections are shown to have been roughened or pitted as by sandblasting; and in Fig. 12 the surfaces have been roughened as by scratches 16f. Due to the surface tension of the antigenic solution, a greater amount of the wet antigenic substance is retained upon the projections 16b than would be the case if the surfaces of the projections were smooth. In any event, the projections 16b are then removed from the solution and the antigenic substance is then dried upon the projections. In the case of most non-viable antigens this drying may be carried out in air at about 37°C. In the case of viable antigens, however, it is preferable to freeze-dry the substance upon the projections. In so doing, the wet substance is first frozen upon the projections by lowering the temperature to as much as minus 45.3°C., whereupon the metal plates with the frozen material thereon are placed in a vacuum chamber and left there for from 7 to 18 hours while the temperature is permitted to rise gradually to about 20°C.

The metal plates 16, with the dried antigenic substance upon the projections 16b thereof, are then secured to the backing members 11.

In the case of the package illustrated in Figs. 3 to 5 this is done simply by flexing the tongues 16a downwardly into the recesses 12d and snapping the tongues past the detents 12e. The detents 12e thereupon retain the plate 16 in place. In the case of the package of Fig. 6 the tongues 16a are riveted in place, as shown, and in the case of the package of Fig. 7, the tabs 16d are pushed through the apertures 12g and are then bent over on the underside of the backing member 11 in order to retain the plate 16 upon the backing member. When the antigenic substance on the projections 16b is of a non-viable type, the assembled plates and backing members and the caps 15 are then appropriately sterilized, such as by steam or ethylene oxide or by any other suitable sterilizing compound. When the antigenic substance is of a viable type, on the other hand, sterilization must be accomplished before the substance is applied to the projections 16b. In the case of the package of Figs. 3 to 5, the cover 15 is pressed downwardly onto the backing member so that the lip or flange 15a snaps over the overhanging shoulder 12b and comes to rest in the annular groove 12c, as best shown in Fig. 5. The cooperation of the shoulder 12b with the flange 15a thereupon retains the cover in place and effectively seals the prepared plate 16 so as to protect the coated projections 16d and prevent contamination of the antigenic substance 17 thereon.

In the case of the packages shown in Figs. 6 and 7, the cap 15 is applied merely by pressing the cap downwardly so that its peripheral edge 15b seats in the groove 12f formed in the upper surface of the backing member 11. The tight fit between the lower edge 15b of the cap and the slot 12f effectively retains the cap in place and maintains the sterile condition of the thin metal plate 16 and the coated projections 16b thereon.

It will be readily appreciated that the present packages may be easily produced in great number and, when effectively sealed as described above, may be stored for substantial periods at various places about the country and may be supplied to physicians in normal channels of trade, as is the case with ordinary medical supplies.

When it is desired to effect a vaccination or skin test inoculation with one of the present packages, the package having the appropriate dried antigenic substance on the projections 16d therein is selected. The skin of the patient is sterilized by alcohol or the like and the cap 15 of the package is then removed. In the case of the package illustrated in Figs. 3 to 5, removal of the cap is facilitated by pressing the centre of the cap with the fingers, thus tending to spread or separate the edges of the cap and making it easier to remove the cap from the backing member 11. In the case of the packages of Figs. 6 and 7, the cap 15 in each case is merely forced out of the groove 12f. This may be facilitated by manually flexing the backing member 11 slightly. Once the cap 15 has been removed from the appropriate package, the sharp, pointed and coated projections 16b are pressed into the skin of the patient in the manner illustrated in Fig. 1, the wings 13 and 14 being pressed by the operator's thumb and second finger and with the index finger bearing upon the central portion 12 of the backing member 11, so that the projections 16b penetrate the skin and carry the dried antigen substance thereinto. The backing member 11 is then held in this position for a few moments by the operator until the lymph and other body fluids in the deeper recesses of the skin dissolve the dried antigenic substances from the points of the projections 16b. With the backing member held as just described, the backing member is gripped between the thumb and second finger and is preferably given a gentle rotary motion while the projections 16b are still embedded in the skin. This tends to insure that all of the antigenic substance is removed from the projections and deposited in or beneath the skin. The vaccination will then have been completed, and the holder 11, with the metal plate 16 still intact thereon, may then be removed from the patient's skin and discarded.

The foregoing description of the present vaccination package with certain variations thereof, and the description of the method by which the packages are prepared and employed in effecting vaccinations or inoculations, and the description of the present new

method of vaccination, has been given for clearness of understanding only and no unnecessary limitations are intended thereby, for it will be apparent to those skilled in the art that various modifications may be made in the packages and in the method of their preparation and use without departing from the scope of the claims appended hereto.

The term "antigenic" as used in the aforesaid description and in the accompanying claims is intended to cover allergenic, antibiotic or other chemotherapeutic substances.

WHAT I CLAIM IS:—

1. A package for use in transcutaneous inoculation, comprising a substantially rigid backing member adapted to be held in the fingers, a skin perforating member secured to said backing member and having a plurality of needle-like projections extending therefrom for simultaneously puncturing the skin at a plurality of points when said backing member is pressed by the fingers against the skin, and protective cover means removably secured to said backing member and covering said skin perforating member for protecting and maintaining said needle-like projections sterile prior to use.

2. A package according to claim 1, wherein the package is prepared for immediate use by having a dried antigenic substance on the needle-like projections of the perforating member, said needle-like projections being adapted simultaneously to puncture the skin at a plurality of points and to introduce said antigenic substance into the body when said backing member is pressed by the fingers against the skin, and the protective cover means being adapted to prevent contamination of said antigenic substance prior to use of the package in inoculation.

3. A package according to claim 1 or 2, wherein the backing member has a substantially flat central portion with a pair of wing-like projections extending from opposite sides thereof by which said backing member may conveniently be held in the fingers, the skin perforating member being secured to said central portion of said backing member, and the protective cover means being removably secured to said central portion of said backing member.

4. A package according to claim 1, 2 or 3, wherein the protective cover means comprises a substantially rigid, imperforate member in the form of a bubble-like cap.

5. A package according to claim 4 wherein the substantially rigid backing member and the protective cap are each formed of moldable synthetic plastic material.

6. A package according to any of claims 1 to 5, wherein the skin perforating member comprises a thin metal plate and the plurality of needle-like projections are punched from said metal plate and project from one side thereof outwardly beyond the level of all adjacent surfaces of said plate and the backing member.

7. A device for use in transcutaneous inoculation, comprising a substantially rigid backing member of moldable synthetic plastic material adapted to be held in the fingers, a thin metal plate secured to said backing member, and a plurality of needle-like projections punched from said metal plate and projecting from one side thereof outwardly beyond the level of all adjacent surfaces of said plate and said backing member, said needle-like projections being adapted simultaneously to puncture the skin at a plurality of points for the purpose of introducing antigenic substances contained thereon into the body when said backing member and said metal plate are pressed by the fingers against the skin.

8. A device according to claim 7 wherein the surfaces of said needle-like projections are scarified so as to increase the amount of antigenic substance that may be received thereon.

9. A device according to claim 7 or 8, wherein the backing member is made of single piece of moldable synthetic plastic material and has a substantially flat central portion with a pair of wing-like projections extending from opposite sides thereof by which said backing member may conveniently be held in the fingers, and means securing said thin metal plate upon said central portion of said backing member.

10. A device according to claim 9, wherein said central portion of said backing member is provided with a pair of recesses and said securing means includes a pair of tongues on said metal plate respectively secured within said recesses.

11. A device according to claim 9, wherein said backing member is provided with a pair of apertures and said securing means includes a pair of tabs formed on said metal plate and respectively extending through said apertures, the free ends of said tabs being bent over to prevent withdrawal of said tabs from said apertures.

12. A device according to claim 9, wherein said thin metal plate is riveted upon said central portion of said backing member.

13. A method of manufacturing a device for use in transcutaneous inoculation, comprising the steps of providing a thin metal plate having a plurality of needle-like projections thereon, dipping said projections into a liquid antigenic substance, and then drying said substance on said projections.

14. The method of claim 13, including the step of freezing said antigenic substance on said projections, and then drying said substance on said projections while said substance is in its frozen state.

15. The method of claim 13 or 14, including the step of securing the metal plate upon a backing member after the antigenic sub-

stance has been dried on said projections.

16. A package for use in transcutaneous inoculation constructed substantially as herein described with reference to the accompanying drawings.

17. A method of manufacturing a device for use in transcutaneous inoculation substantially as herein described.

STEVENS, LANGNER, PARRY & ROLLINSON,
Chartered Patent Agents,
Agents for the Applicant.

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Published by The Patent Office, 25, Southampton Buildings, London, W.C.2, from which copies may be obtained.

FIG. 1

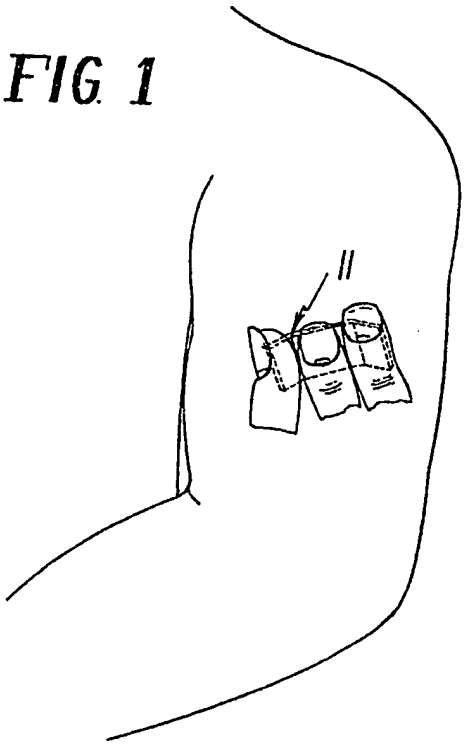


FIG. 2

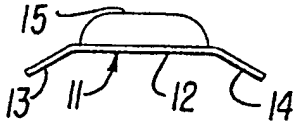


FIG. 3

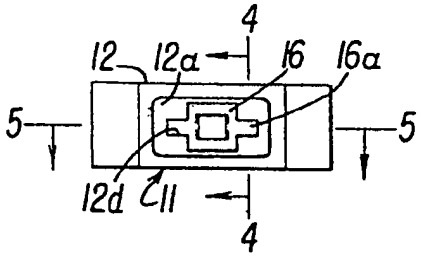


FIG. 4

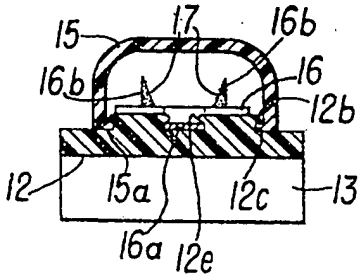
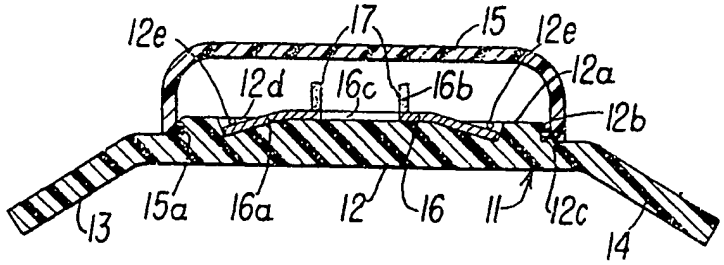


FIG. 5



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SHEETS 1 & 2

FIG. 6

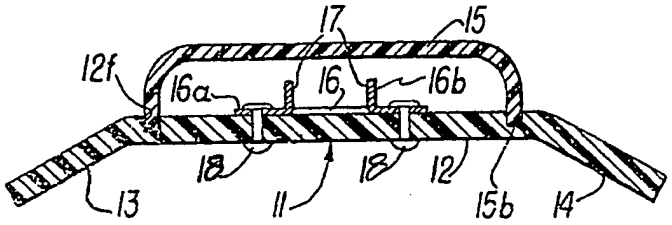


FIG. 7

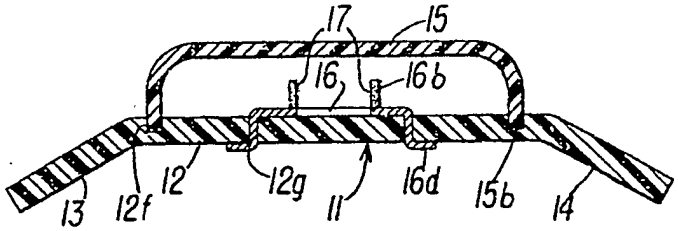


FIG. 8

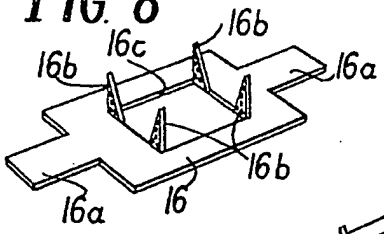


FIG. 9

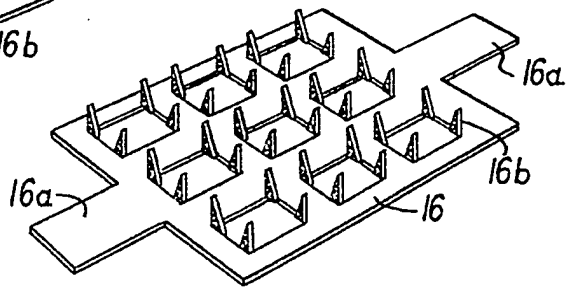


FIG. 10

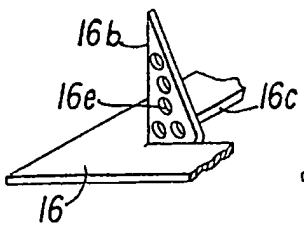


FIG. 11

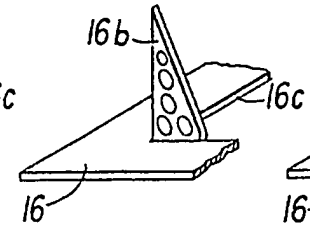
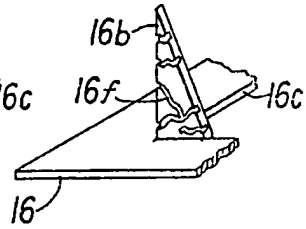


FIG. 12



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SHEETS 1 & 2

FIG. 1

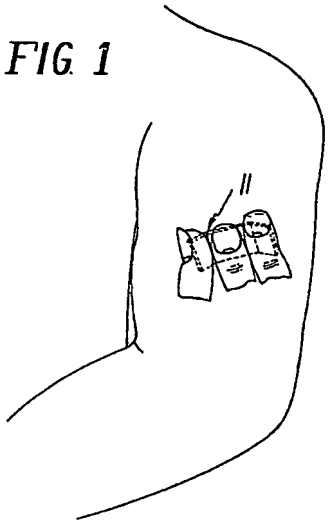

FIG. 2

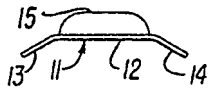

FIG. 3

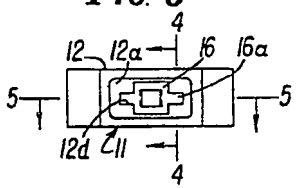

FIG. 4

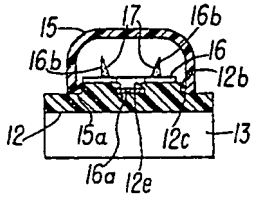

FIG. 5

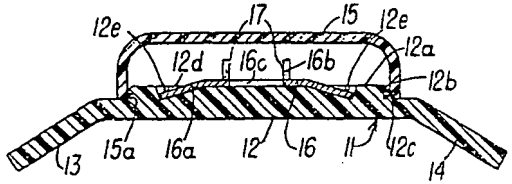

FIG. 6

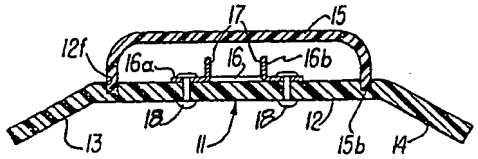

FIG. 7

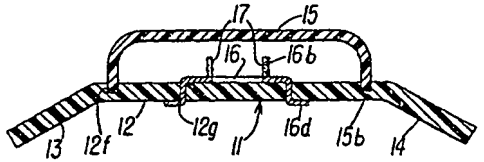

FIG. 8

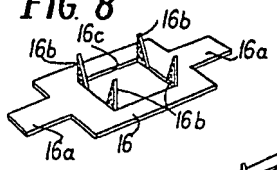

FIG. 9

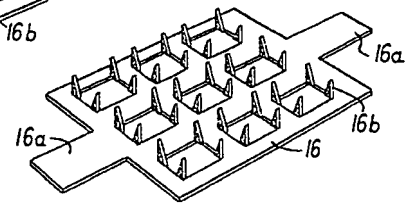

FIG. 10

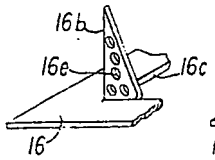

FIG. 11

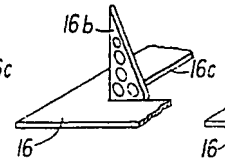

FIG. 12